ILMN Q2 Fiscal Year 2022 Earnings Call
Prepared Remarks – August 11, 2022

Salli Schwartz, *Investor Relations*

Hello everyone, and welcome to our earnings call for the second quarter of 2022.

During the call today, we will review the financial results released after the close of the market, and offer commentary on our commercial activity, after which we will host a question and answer session. If you have not had a chance to review the earnings release, it can be found in the Investor Relations section of our website at illumina.com.

Participating for Illumina today will be Francis deSouza, President and Chief Executive Officer, and Joydeep Goswami, Chief Strategy and Corporate Development Officer as well as Interim Chief Financial Officer. Francis will provide an update on the state of Illumina's business and Joydeep will review our financial results which include GRAIL.

As a reminder, pending the outcome of the European Commission's investigation into Illumina's acquisition of GRAIL, the Commission has adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities for an interim period. Compliance with the order is monitored by an independent Monitoring Trustee. During this period, Illumina and GRAIL are not permitted to share confidential business information unless legally required, and GRAIL must be run independently, exclusively in the best interests of GRAIL. Commercial interactions between the two companies must be undertaken at arm's length.

This call is being recorded and the audio portion will be archived in the Investor section of our website. It is our intent that all forward-looking statements regarding our financial results and commercial activity made during today's call will be protected under the Private Securities Litigation Reform Act of 1995.

Forward-looking statements are subject to risks and uncertainties. Actual events or results may differ materially from those projected or discussed. All forward-looking statements are based upon current available information, and Illumina assumes no obligation to update these statements.

To better understand the risks and uncertainties that could cause actual results to differ, we refer you to the documents that Illumina files with the Securities and Exchange Commission, including Illumina's most recent forms 10-Q and 10-K.

With that, I will now turn the call over to Francis.

Francis deSouza, *President & Chief Executive Officer*

Thank you, Salli. Good afternoon, everyone.

Illumina delivered revenues of $1.16 billion in the second quarter, up 3% year-over-year, or 5% on a constant currency basis.

While sequencing activity across our markets was robust in the second quarter – with sequencing runs on our connected high- and mid-throughput platforms growing more than 15% year-over-year, and clinical growing even faster – our second quarter results were impacted by macroeconomic challenges that we expect to play out over the next couple of quarters. Specifically, some customers experienced supply chain pressures that delayed their lab expansions, and others managed inventory and capital more conservatively. We also saw adverse effects of foreign exchange, and anticipated COVID-related shutdowns in China. The robust sequencing activity levels, underlying growth of our target markets, and our conversations with customers across the globe indicate these dynamics are temporary.

During the quarter, we also made terrific progress on our innovation roadmap and are poised to soon deliver the next-generation of breakthrough technologies that will fuel the next era of genomics.

Turning now to performance across our platforms:

In high-throughput, NovaSeq shipments in Q2 grew 23% year-over-year, our highest second quarter ever. Consistent with prior quarters, Clinical customers, primarily in oncology testing, drove half of our NovaSeq shipments.

In mid-throughput, NextSeq 1K/2K orders were up 20% year-over-year. Despite some shipments shifting from Q2 to Q3 due to supply delays, Q2 NextSeq 1k/2k shipments increased slightly year-over-year.

Low-throughput shipments were relatively flat year-over-year, even with the comparison to last year's COVID surveillance driven volume.

Turning to our markets, we continue to gain traction in Clinical, with sequencing consumables shipments for the second quarter up 11% year-over-year, and all of our Clinical markets contributing to the increase.

As I mentioned earlier, we have seen continued growth in our oncology markets. In Q2, oncology consumables grew almost 20% year-over-year. An area of note is our market-leading True Sight Oncology assay. Shipments of TSO grew 45% year-over-year, and we now have delivered distributed comprehensive genomic profiling tests to every major market in the world. We have worked closely with large evidence programs to facilitate clinical utility and drive market access, and we have more than 10 pharma partners developing CDx claims with us. Most recently, we expanded our portfolio by codeveloping a new TSO 500 HRD test with Merck that leverages Illumina's work with Myriad Genetics. We also codeveloped a pan-cancer companion diagnostic for TSO Comprehensive EU with Bayer.

Also in oncology, June marks the one-year anniversary of GRAIL's launch of Galleri. In that time, Galleri delivered the fastest-ever first year revenue ramp of a cancer screening test. GRAIL continues to drive progress in clinical evidence generation and commercial use of their multi-cancer early detection test, Galleri.

The number of U.S. health systems partnering with GRAIL to offer Galleri continues to grow, most recently with the addition of Mercy, one of the 25 largest U.S. health systems, and Ochsner Health, the largest Gulf South health system.

Also, GRAIL recently partnered with AstraZeneca to develop companion diagnostic tests that will identify patients with high-risk, early-stage disease. AstraZeneca will use GRAIL technology to recruit patients with early-stage cancer for AstraZeneca's clinical studies, making cancer medicines available when there is greater potential to transform outcomes.

More broadly, the trials currently underway for Galleri continue to progress. The NHS Galleri trial in the UK, the largest multi-cancer early detection study, has enrolled 140,000 volunteers in just over 10 months – an unprecedented speed, especially for a trial of this size. Pending successful completion of the trial, the NHS plans to roll out Galleri to an additional 1 million people starting in 2024. This collaboration supports the NHS Long Term Plan to transform cancer care with three in four cancers diagnosed at an early stage by 2028. Additionally, GRAIL has completed a final analysis of its PATHFINDER study, with data to be presented at the European Society of Medical Oncology Congress, September 9th-13th.

GRAIL has made substantial progress building a network of partners that will support ongoing adoption of Galleri, but commercial progress is proceeding at a more measured pace as health systems ramp up. For these reasons, GRAIL has revised its revenue guidance for full year 2022 to a range of $50 million to $70 million.

Turning to infectious disease and microbiology, the genomic surveillance infrastructure built on Illumina instruments during the pandemic in more than 100 countries is now being used for other diseases, like monkeypox. This network is enabling a quicker genetic assessment of this new disease, as momentum continues to build for a robust global pathogen infrastructure. We are expanding our surveillance portfolio accordingly. In June, we provided select customers access to our novel viral surveillance panel, based on workflows implemented for COVID-19. The panel provides targeted

sequencing for the 66 most critical viruses of global public health concern, including monkeypox and polio, and will be commercially available later this year.

Our Research and Applied markets were relatively flat year-over-year with growth in the Americas and APJ offset by declines in EMEA and China. In the quarter, we announced our partnership with Precision Health Research Singapore, or PRECISE, to sequence whole genomes of 100,000 Singaporean participants. Together, we will develop Southeast Asia's most comprehensive population study and gather deep insights into Asian genomic diversity and key genetic, social, environmental, and other factors associated with disease.

Before I update you on further advances in our innovation roadmap, I'll turn the call over to Joydeep.

Joydeep Goswami, *Chief Strategy and Corporate Development Officer, Interim Chief Financial Officer*

Thanks, Francis.

As a reminder, our second quarter financial results include the consolidated financial results for GRAIL. I'll start by reviewing our consolidated financial results, followed by segment results for Core Illumina and GRAIL, then conclude with additional remarks on our current outlook for 2022. I will be discussing non-GAAP results which include stock-based compensation. I encourage you to review the GAAP reconciliation of these non-GAAP measures which can be found in today's release and in supplementary data available on our website.

In the second quarter, consolidated revenue was $1.16 billion, up 3% year-over-year, or 5% on a constant currency basis, net of the effects of hedging. Revenue was impacted by the macroeconomic factors that Francis referenced. As you know, we had anticipated the headwinds from the China shutdowns, the negative impact of Fx, and slowing COVID surveillance. Each of these was slightly worse than we expected and collectively they drove one-quarter of the variance between our expectations and actual results. The remainder of this variance was driven by the lab expansion delays encountered by a few of our large customers as a result of global supply chain constraints as well as customer inventory and capital management.

Nonetheless, overall sequencing activity on our connected instruments was strong in the second quarter, with sequencing runs on our high and mid-throughput instruments growing more than 15% year-over-year. We believe this is a useful reference that shows the general activity trend across our installed base and is directionally correlated with revenue over time.

For the second quarter, GAAP net loss was $535 million, or a loss of $3.40 per diluted share, which included $609 million in legal contingencies recorded in Q2 due to the potential fine that the European Commission may impose related to our GRAIL acquisition, and settlement of our litigation with BGI.

Non-GAAP earnings were $91 million, or $0.57 per diluted share, including dilution from GRAIL's non-GAAP operating loss of $152 million for the quarter.

Our non-GAAP tax rate was 25.8%, which increased 790 basis points year-over-year and 800 basis points from Q1 2022, primarily due to the increased impact of R&D expense capitalization requirements implemented by the Tax Cuts and Jobs Act of 2017.

Our non-GAAP weighted average diluted share count for the quarter was approximately 159 million.

Moving to segment results, I will start by discussing the financial results of Core Illumina:

Core Illumina revenue of $1.16 billion grew 3% year-over-year, or 4% on a constant currency basis, net of the effects of hedging.

Core Illumina sequencing consumables revenue grew 6% year-over-year to $744 million, driven by almost 20% growth in oncology testing. Core consumables growth more than offset headwinds from lockdowns in China, the completion of the UK BioBank program in Q3 2021, reductions in COVID surveillance, and negative FX impacts.

Sequencing instruments revenue for Core Illumina grew 1% year-over-year to $190 million, driven by 23% growth in NovaSeq shipments, offset by a 14% decrease in mid-throughput shipments year-over-year. The decrease in mid-throughput shipments was primarily due to headwinds from COVID surveillance and COVID lockdowns in China, with NextSeq 1K/2K growth more than offset by a decrease in NextSeq 550. NextSeq 1K/2K instruments continued to grow year-over-year, and the growth would have been stronger had it not been for temporary supply constraints that delayed shipments into the third quarter. NextSeq 1K/2K orders were up 20% year-over-year with continuing strong adoption of our newest platform.

During the second quarter, COVID surveillance contributed approximately $25 million in sequencing consumables revenue and $2 million in incremental instruments revenue, representing a decline of 55% year-over-year. This decline was driven by lower than expected testing samples and the expected decline in instrument shipments as Covid surveillance capacity was largely established in 2021.

Core Illumina sequencing service and other revenue of $125 million was down 2% year-over-year driven by $20 million of one-time revenue recognized in 2021 from NIPT royalties received related to a patent litigation settlement, partially offset by increased instrument service contracts and contributions from oncology co-development partnerships.

Moving to regional results for Core Illumina:

Revenue for the Americas region was $633 million, up 7% year-over-year, primarily due to NovaSeq strength, with continued demand from oncology testing customers driving instrument placements and consumables growth. Growth in the region was nonetheless lower than expected primarily due to customer lab expansion delays and inventory and capital management we've mentioned during the call.

EMEA revenue of $308 million represented a 4% decrease year-over-year, but a 1% increase on a constant currency basis, net of the effect of hedges. Sequencing growth driven by clinical and large scale research projects was more than offset by the UK BioBank program in 2021 and a decline in Covid-19 surveillance revenue. Cumulatively, these significant headwinds, and FX, negatively impacted year-over-year revenue growth by 20 percentage points.

Greater China revenue of $118 million represented an 11% decrease year-over-year, and a 10% decrease on a constant currency basis. This was slightly more negative than the approximately $35 million headwind to guidance we provided last quarter. As expected, the region continued to be impacted by prolonged Covid-19 restrictions and shutdowns that began in March this year.

Finally, APJ revenue of $97 million grew 14% year-over-year, or 20% on a constant currency basis, net of the effects of hedges. Growth in the region was primarily due to increased NovaSeq shipments, which doubled year-over-year, driven by large-scale research project demand, as well as strength in NIPT and oncology testing.

Moving to the rest of the Core Illumina P&L:

Core Illumina non-GAAP gross margin of 69.8% decreased 200 basis points year-over-year primarily due to less fixed cost leverage on lower manufacturing volumes, margin impact from one-time revenue from a patent litigation settlement in 2021, and increased freight costs attributable to broader global supply chain pressures. These factors were partially offset by a more favorable product mix, as well as a number of productivity initiatives we continue to execute.

Core Illumina non-GAAP operating expenses of $519 million were up $48 million year-over-year due primarily to headcount growth and investments we are making in R&D to support the continued advancement of our innovation roadmap. Despite the year-over-year increase, non-GAAP Core Illumina operating expenses were lower than we originally planned as a result of lower performance-based compensation expense given our lower revenue outlook and cost containment initiatives focused on select hires and discretionary spend, including travel.

Transitioning to the financial results for GRAIL:

GRAIL revenue of $12 million for the quarter consisted primarily of Galleri test fees. GRAIL non-GAAP operating expenses totaled $156 million for the quarter and consisted primarily of expenses related to headcount and clinical trials . These expenses were lower than expected as GRAIL managed its project spend in light of its lower quarterly outlook.

Moving to consolidated cash flow and balance sheet items:

- Cash flow from operations was $125 million;
- DSO was 50 days compared to 46 days last quarter due to revenue linearity;
- Second quarter 2022 capital expenditures were $71 million and free cash flow was $54 million;
- We did not repurchase any common stock in the quarter.

We ended the quarter with approximately $1.3 billion in cash, cash equivalents and short-term investments.

Moving now to 2022 guidance:

We have revised our outlook for the full year to represent the macroeconomic factors we observed through early August and we assume will continue for the rest of the year.

We now expect full year 2022 consolidated revenue to grow in the range of 4% - 5%, including Core Illumina revenue growth in the range of 3.5% - 4.5%, and GRAIL revenue of $50 - $70 million.

For the full year, at the midpoint of our revenue guidance range, we now expect Core Illumina sequencing revenue to grow approximately 4.5%. This includes intercompany sales to GRAIL of approximately $25 million, which are eliminated in consolidation.

Within Core Illumina sequencing revenue, we now expect:

- Instrument growth of 1.5% and consumables growth of 5%, which reflects NovaSeq pull-through in the range of $1.1 to $1.2 million per system for 2022.
- We continue to expect pull-through for NextSeq 1000/2000 in the range of $130,000 to $180,000 per system and for NextSeq 550 in the range of $100,000 to $150,000 per system.
- For MiSeq, we continue to expect pull-through in the range of $35,000 to $45,000 per system and for MiniSeq, we continue to expect pull-through in the range of $20,000 to $25,000 per system.

We now expect revenue from Covid surveillance in the range of $110 to $130 million. While we anticipated a decline in COVID surveillance in 2022, the deceleration has occurred at a more rapid pace than we previously forecasted.

As we navigate the macroeconomic factors we've mentioned, we are implementing multiple strategies, including prioritizing key innovation investments and critical hires, while pausing investments that can be made at later times. We have retained all critical investments in in our innovation roadmap, including NovaSeq Dx, Chemistry X, our Infinity long read technology, and our TSO portfolio.

We now expect consolidated non-GAAP operating margin in the range of 11.5% - 12% and Core Illumina non-GAAP operating margin in the range of 24.5% - 25%. We expect a consolidated non-GAAP tax rate of approximately 14%, which continues to assume that the R&D expense capitalization requirements implemented by the Tax Cuts and Jobs Act of 2017 will be repealed or deferred in Q4.

And, we now expect non-GAAP earnings per diluted share in the range of $2.75 to $2.90, which includes dilution from GRAIL non-GAAP operating loss of approximately $610 million, in line with previous expectations. Lastly, we continue to expect diluted shares outstanding of approximately 159 million shares for 2022.

For the third quarter of 2022:

- We expect consolidated revenue to be flat to 1% higher year-over-year from the third quarter of 2021.
- We expect consolidated non-GAAP operating margin to be approximately 5%.
- We expect Core Illumina non-GAAP operating margin to be approximately 20%.
- We expect consolidated non-GAAP tax rate to be approximately 22%, which continues to reflect the negative impact from the R&D capitalization requirements we expect will be repealed or deferred in the fourth quarter of this year.

And lastly, we expect diluted shares outstanding to be in line with our full year 2022 guidance of approximately 159 million shares.

I will now hand the call back over to Francis for his final remarks.

Francis deSouza, *President & Chief Executive Officer*

Thanks, Joydeep. Turning to our innovation roadmap… We have significant opportunities to reimagine the power and potential of genomics.

Development and registration activities for NovaSeq Dx, the first ever high-throughput clinical sequencer, are progressing as planned and on track for a Q4 launch. We continue to get good feedback from initial customers on our Infinity long-read technology, with many saying it has the potential to replace on-market long reads for a broad range of applications, including human rare diseases. Infinity is on track to be available later this year for early access customers.

In multiomics, our partnership with Somalogic to accelerate NGS into proteomics is progressing, and we expect to deliver our ultra-high-throughput, ultra-high-plexity assay in 2024.

Turning now to Chemistry X, our next generation breakthrough SBS chemistry… we have made fantastic progress over the last quarter. We are now producing flow cells using our new manufacturing process based on 300 millimeter wafers. We've successfully tested Chemistry X on the new flow cells, and the results exceed our expectations for quality, cost and speed.

We are excited to showcase these breakthroughs, and reveal how they come to life, at the Illumina Genomics Forum. And we look forward to hosting you at our Investor Day on October 3rd, where we will discuss these technologies and our long-term growth strategies. If you haven't already registered, please be sure to do so soon.

Statement regarding use of non-GAAP financial measures

The company reports non-GAAP results for diluted earnings per share, net income, gross margin, operating expenses, including research and development expense, selling general and administrative expense and legal contingencies, operating income (loss), operating margin, gross profit, other income (expense), constant currency revenue growth, and free cash flow (on a consolidated and, as applicable, segment basis for our Core Illumina and GRAIL segments) in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The company's financial measures under GAAP include substantial charges such as amortization of acquired intangible assets among others that are listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release, as well as the effects of currency translation. Management has excluded the effects of these items in non-GAAP measures to assist investors in analyzing and assessing past and future operating performance, including in the non-GAAP measures related to our Core Illumina and GRAIL segments. Additionally, non-GAAP net income and diluted earnings per share are key components of the financial metrics utilized by the company's board of directors to measure, in part, management's performance and determine significant elements of management's compensation.

The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the tables of this release.

Use of forward-looking statements

This release may contain forward-looking statements that involve risks and uncertainties. Among the important factors to which our business is subject that could cause actual results to differ materially from those in any forward-looking statements are: (i) the impact to our business and operating results of the COVID-19 pandemic; (ii) changes in the rate of growth in the markets we serve; (iii) the volume, timing and mix of customer orders among our products and services; (iv) our ability to adjust our operating expenses to align with our revenue expectations; (v) our ability to manufacture robust instrumentation and consumables; (vi) the success of products and services competitive with our own; (vii) challenges inherent in developing, manufacturing, and launching new products and services, including expanding or modifying manufacturing operations and reliance on third-party suppliers for critical components; (viii) the impact of recently launched or pre-announced products and services on existing products and services; (ix) our ability to further develop and commercialize our instruments, consumables, and products, including Galleri, the cancer screening test developed by GRAIL, to deploy new products, services, and applications, and to expand the markets for our technology platforms; (x) the risks and costs associated with the integration of, and our ability to integrate, GRAIL's business successfully to achieve anticipated synergies, including the restrictions on integration during any hold separate period or any delay in integration following any hold separate period; (xi) the risk that disruptions from the consummation of our acquisition of GRAIL or any associated legal or regulatory proceedings or obligations will harm our business, including current plans and operations; (xii) potential adverse reactions or changes to business relationships resulting from the consummation of our acquisition of GRAIL; (xiii) the risk of incurring fines associated with the consummation of our acquisition of GRAIL and the possibility that we may be required to divest all or a portion of the assets or equity interests of GRAIL on terms that could be materially worse than the terms on which we acquired GRAIL; (xiv) our ability to obtain approval by third-party payors to reimburse patients for our products; (xv) our ability to obtain regulatory clearance for our products from government agencies; (xvi) our ability to successfully partner with other companies and organizations to develop new products, expand markets, and grow our business; (xvii) our ability to successfully identify and integrate acquired technologies, products, or businesses; (xviii) the application of generally accepted accounting principles, which are highly complex and involve many subjective assumptions, estimates, and judgments and (xix) legislative, regulatory and economic developments, together with other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update these forward-looking statements, to review or confirm analysts' expectations, or to provide interim reports or updates on the progress of the current quarter.